



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0742]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with drug establishment registration and product listing requirements.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2011-N-0742 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution." Received

comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution--21 CFR

Part 207

OMB Control Number 0910-0045--Revision

This information collection supports implementation of drug establishment registration and listing requirements governed by FDA. These requirements are set forth in section 510 of

the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) and section 351 of the Public Health Service Act (42 U.S.C. 262) and provide for electronic submission of information. Agency regulations implementing these provisions are found in part 207 (21 CFR part 207) and set forth the scope, applicability, and content of information to be included in submissions. Except as provided in § 207.65, all information submitted under part 207 must be transmitted to FDA in an electronic format by using our electronic drug registration and listing system, in a form that we can process, review, and archive. For more information pertaining to drug establishment registration and listing, we invite you to visit our website at: <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site>.

We are revising the information collection to include the collection of certain information required by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Section 3112 of the CARES Act requires that registrants under section 510 of the FD&C Act must annually report the amount of each drug listed that was manufactured, prepared, propagated, compounded, or processed for commercial distribution. Section 3112(e) also authorizes FDA to require that registrants report this information electronically. Finally, section 3112(e) granted FDA the authority to require that registrants report this information at the time a public health emergency is declared.

To assist respondents to the information collection with the current electronic reporting requirements, we issued the guidance document entitled “Providing Regulatory Submissions in Electronic Format--Drug Establishment Registration and Drug Listing” (June 2009), available from our website at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-drug-establishment-registration-and-drug-listing>. Guidance on the submission of the reporting required in section 3112(e) of the CARES Act is included on CDER’s 2021 guidance agenda available from our website at: <https://www.fda.gov/media/134778/download>. Agency guidance documents are issued

consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Registration under part 207: Unless otherwise exempt under section 510(g) of the FD&C Act or § 207.13, all manufacturers, repackers, relabelers, and salvagers must register each domestic establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, and each foreign establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug that is imported or offered for import into the United States. When operations are conducted at more than one establishment and common ownership and control among all the establishments exists, the parent, subsidiary, or affiliate company may submit registration information for all establishments. Private label distributors who do not also manufacture, repack, relabel, or salvage drugs are not required to register under part 207. We will accept registration or listing information submitted by a private label distributor only if the distributor is acting as an authorized agent for and submitting information that pertains to an establishment that manufactures, repacks, relabels, or salvages drugs.

Listing requirements under part 207: Under § 207.41, registrants must list each drug that it manufactures, repacks, relabels, or salvages for commercial distribution. Each domestic registrant must list each such drug regardless of whether the drug enters interstate commerce. When operations are conducted at more than one establishment, and common ownership and control exists among all the establishments, the parent, subsidiary, or affiliate company may submit listing information for any drug manufactured, repacked, relabeled, or salvaged at any such establishment. A drug manufactured, repacked, or relabeled for private label distribution must be listed in accordance with the requirements in § 207.41(c).

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden¹

Information Collection Activity; 21 CFR/Statutory Citation	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
--	--------------------	---------------------------------	------------------------	-----------------------------	-------------

Initial establishment registration; §§ 207.17, 207.21, and 207.25	1,480	2	2,960	1	2,960
Annual review and update of registration information (including expedited updates); § 207.29)	10,000	1	10,000	0.5 (30 minutes)	5,000
Initial listing (including National Drug Code); §§ 207.33, 207.41, 207.45, 207.49, 207.53, 207.54, and 207.55	1,713	7.28	12,470	1.5	18,705
June and December review and update (or certification) of listing; §§ 207.35 and 207.57)	5,300	20	106,000	0.75 (45 minutes)	79,500
Waiver requests; § 207.65	1	1	1	0.5 (30 minutes)	1
Public disclosure exemption request; § 207.81(c))	100	1	100	1	100
Manufacturing amount information; Section 3112 CARES Act	12,800	22.5	288,000	0.25 (15 minutes)	72,000
Total			419,531		178,266

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden¹

Information Collection from Guidance Recommendations	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Preparing Standard Operating Procedures for creating and uploading the Structured Product Labeling file	1,000	1	1,000	40	40,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

According to internal data, we estimate 1,480 respondents will submit 2,960 new establishment registrations annually. We estimate that 10,000 registrants will provide 10,000 annual reviews and updates of registration information (including expedited updates) or reviews and certifications that no changes have occurred. The estimates include the registration of establishments for both domestic and foreign manufacturers, repackers, relabelers, and drug product salvagers, and registration information submitted by anyone acting as an authorized agent for an establishment that manufactures, repacks, relabels, or salvages drugs. The estimates include an additional 80 positron emission tomography drug producers who are not exempt from registration and approximately 30 manufacturers of plasma derivatives.

We assume 1 hour is necessary for registrants to submit initial registration information electronically for each new establishment. We assume 30 minutes is necessary for each annual review and update of registration information (including any expedited updates) or each review and certification that no changes have occurred. Our estimate reflects the average amount of time and effort necessary to register a domestic or foreign establishment, and the average amount of time and effort necessary to review and update registration information, or review registration information and certify no changes have occurred.

Based on the number of drugs listed annually since June 2009, we estimate 1,713 registrants will report approximately 12,469 new listings annually (including the information submitted to obtain a labeler code and to reserve a National Drug Code (NDC) for future use). Based on the number of drugs in our listing database and the current number of changes to listing information submitted, we estimate 5,300 registrants will each report 20 reviews and updates (including the information submitted to revise an NDC) for a total of 106,000 annually. The estimates for the number of drug listings include both domestic and foreign listings, listings submitted by registrants for products sold under their own names as well as products intended for private label distribution, and information submitted related to an NDC and to obtain a labeler code. The estimate for the number of drugs subject to the listing requirements includes positron emission tomography drugs and approximately 30 plasma derivatives. The estimates for the number of June and December reviews and updates of listing information include the number of changes to drug characteristics pertaining to the drug product code to obtain a new NDC and the reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii) (21 CFR 314.81(b)(3)(iii)).

Based on our experience with electronically listing submissions since June 2009, we assume it takes 1 hour and 30 minutes to submit information electronically for each drug listed for the first time (for both foreign and domestic registrant listings). These estimates are an average of the time it will take manufacturers, repackers, relabelers, and drug product salvagers,

with drug product salvagers taking considerably less time than manufacturers. The estimates include the time for submitting the content of labeling and other labeling in an electronic format (for drugs subject to an approved marketing application, the electronic submission of the content of labeling under § 314.50(l)(1)(i) is approved under OMB control number 0910-0001). We assume it takes 45 minutes for each June and December review and update. These estimates represent the average amount of time to review and update listing information or to review and certify that no changes have occurred. The estimates include the time for submitting any labeling for each drug, changes to the drug's characteristics submitted for a new NDC, and reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii).

Finally, although we expect most respondents will already have prepared a standard operating procedure (SOP) for the electronic submission of drug establishment registration and drug listing information, we estimate each year additional firms will need to create an SOP as recommended in the guidance. We therefore estimate 1,000 firms will expend approximately 40 hours to prepare, review, and approve an SOP, for a total of 40,000 hours annually.

While we retain the currently approved burden estimates for information collection associated with provisions in part 207, we have adjusted our estimate upward by 72,000 hours and 288,000 responses to account for information collection associated with the new manufacturing amount information element required by the CARES Act.

Dated: May 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.